

quiescent state. Support for this amendment may be found at the very least in the specification on page 47, lines 4-6.

Turning to the Office Action, Applicants appreciate withdrawal of the rejections under 35 U.S.C. §112, second paragraph, as well as the indication of allowable subject matter in newly submitted claims 80 and 82. However, Applicants respectfully submit that all claims pending in the subject application are allowable for the following reasons.

First, Claims 1-17, 24, 25, 61, 63 and 79-82 remain rejected under the judicially created doctrine of obviousness type double patenting as being unpatentable over claims 103-126 of allowed application No. 08/781,752. This application has since issued as U.S. Patent No. 5,945,577, therefore, this rejection is no longer provisional. The requisite terminal disclaimer will be submitted shortly.

Claims 1-17, 24, 25, 29, 30, 32, 34, 46-48, 50, 52, 54, 55, 57, 59, 61-63, 78, 79 and 81 “remain” rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for methods where the differentiated cell or donor nucleus has been expanded in culture, allegedly fails to enable the methods where the differentiated cell has not been expanded in culture. Applicants respectfully traverse this rejection.

First, applicants respectfully note that this appears to be a new ground for rejection, because the original rejection under 35 U.S.C. §112, set forth in the Office Action dated August 4, 1999, was not a scope rejection and furthermore, made no mention (that applicants can see) of differentiated cells versus those that were expanded in culture. Nevertheless, it is applicant’s understanding that this issue was resolved during the Examiner interview, and that it is now clear that the donor cell need not be expanded in culture. Therefore, withdraw of the rejection is respectfully requested.

As a side issue, applicants acknowledge the Examiner’s comments in response to applicant’s assertion of the generic nature of the invention, i.e., “This [particular species] limitation is instituted by applicant and not by the examiner. If broader claims are wanted, then it is up to the applicant to point out and claim that which they consider to be the invention.” Applicants regret the lack of communication regarding this point, but respectfully reiterate that the present claims (which applicants do indeed desire to patent) are drawn specifically to pigs. Applicant’s point in the previous Reply (filed Feb. 4, 2000) was, that the pig, or porcine, was included expressly as a species that was amenable to use in the claims of the allowed parent application (now U.S. Patent No. 5,945,577, see claim 13). Applicants made this point in response to the broad enablement rejection originally set forth, to the extent that this original rejection was inconsistent with the allowance of the parent

application given that porcine were expressly included. However, given that the original enablement rejection has been replaced with the scope of enablement rejection discussed above, applicant's point regarding the inconsistency of the original rejection is now moot.

Claims 19, 20, 27, 28, 65 and 71-75 remain rejected under 35 U.S.C. §102(b) as being allegedly anticipated by several references for reasons of record. Similarly, claim 33 remains rejected under 35 U.S.C. §103(a) as being unpatentable over Strojek et al. for reasons of record. Essentially, it is the Examiner's opinion that arguing that the claimed products have an identical genotype to a prior existing product is not persuasive because it is basically the same product made by a different process, and that the cloning methods of the present application fail to provide any patentable alteration to the pigs, pig embryos, pig fetuses, pig offspring, pig cell lines, and differentiated pig cells. Applicants respectfully traverse the rejection.

Applicants still believe that the fact that the pigs, pig fetuses, embryos, etc. of the present invention have the same genotype as a prior existing pig, pig fetus, pig embryo, etc. is indeed a novel attribute because no pig, pig fetus, embryo, etc. ever had this characteristic prior to the advent of cloning technology. Nevertheless, without necessarily agreeing with the Examiner's position, applicants respectfully submit that the cloned pigs, pig fetuses, embryos etc. have several features which distinguish them from naturally derived pigs, i.e., those derived by sexual reproduction.

In this regard, applicants have attached to this Reply a recent Science article which reports that the life span of somatic cells is extended via nuclear transfer (Lanza et al., Apr 28, 2000, "Extension of cell life-span and telomere length in animals cloned from senescent somatic cells," Science, 288(5466): 665-9). This novel attribute is demonstrated by showing that cells from cloned animals have an increased population doubling capacity compared to age-matched controls. For instance, according to the Science article, nuclear transfer extended the replicative capacity of donor cells having zero to four population doublings remaining to greater than 90 population doublings. This extended longevity characteristic is not merely a function of nuclear transfer as Wilmut et al. reported contrary results with Dolly (for which he had used a quiescent donor cell). Moreover, as reported in the Science (2000) article, this longevity is associated with physical attributes such as extended telomeres relative to age-matched controls, and a level of early population doubling complementary DNA-1 (EPC-1) that was 3.5 to 5-fold higher than age-matched and newborn control animals.

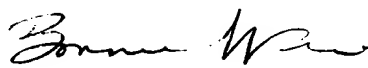
The fact that cloned transgenic porcines can be physically distinguished from animals produced by sexual reproduction, i.e., on the basis of both population doublings and telomere length provides convincing evidence that cloned animals, and the tissues and organs derived from them, are patentably distinct from tissues, organs and animals produced by other methods. Applicants would be happy to amend the claims and the application to reflect these novel attributes in order to more fully distinguish the cloned animals, fetuses, embryos and cells from those that are not derived by cloning if the Examiner believes this would be appropriate. In this regard, applicants respectfully note that the Federal Circuit has held that "the disclosure in a subsequent patent application of an inherent property of a product does not deprive that product of the benefit of an earlier filing date. Nor does the inclusion of a description of that property in later-filed claims change this reasonable result." See *Kennecott Corp. v. Kyocera International, Inc.*, 5 USPTO 2d 1194, 1198 (Fed. Cir. 1987). It follows that where an earlier-disclosed method inherently produces a later-claimed product, "the insertion of disclosure concerning the product is not new matter." *Id.* At 1197. Reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) and 103(a) are respectfully requested.

This Reply is fully responsive to the Office Action dated May 16, 2000. A Notice of Allowance is respectfully requested. If there are any further issues relating to this Reply or to the application in general, the Examiner is respectfully requested to contact the undersigned so that prosecution of this application may be expedited.

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17 and 1.21 that may be required by this paper, and to credit any over payment, to Deposit Account No. 50-1390. This paper is submitted in duplicate.

Respectfully submitted,

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